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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/522,373	03/10/00	LOEB	L 16336-000730

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TOWNSEND AND TOWNSEND AND CREW
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EXAMINER	
SHIBUYA, M	
ART UNIT	**PAPER NUMBER**
1635	7

DATE MAILED: 08/01/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

File Copy

Office Action Summary	Application No. 09/522,373	Applicant(s) LOEB ET AL.
	Examiner Mark L. Shibuya	Art Unit 1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *May 14, 2001*.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-67* is/are pending in the application.

4a) Of the above, claim(s) *19-44, 51-62, 65, and 67* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-18, 45-50, 63, 64, and 66* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of Group I, claims 1-18, 45-50, 63-64 and 66, and species flavivirus /HCV and 5-hydroxyuridine, in Paper No. 6, filed 5/14/01, is acknowledged. The traversal is on the ground(s) that "the four groups set forth by the Examiner all stem from a common concept and theory, and are thus related. As such, prosecution of the claims of Groups I-IV would not place a substantially greater burden or the Examiner." This is not found persuasive because applicant does not identify the common concept and theory; and because a method of increasing mutation rates of a virus in a cell is different from methods of detecting the mutagenic potential of a ribonucleoside analog or making a mutagenic riboside or viral particles comprising RNA nucleoside analogs.

The requirement is still deemed proper and is therefore made FINAL.

Specification

2. The specification is objected to because the specification at p. 14, line 1, recites the terminology "http://www.ncbi.nlm. nih.gov/". Embedded hyperlinks and/or other forms of browser-executable code are impermissible and must be deleted. The attempt to incorporate subject matter into the patent application by reference to a hyperlink and/or other forms of browser-executable code is considered to be an improper incorporation by reference. See MPEP 608.01(p), paragraph I regarding incorporation by reference. Furthermore if the application should issue and be placed on the Office web page, the URL may be interpreted as a valid HTML

code and become a live web link, transferring an user to a commercial web site. Office policy does not permit the Office to link to any commercial site because the Office exercises no control over the organization, views or accuracy of the information contained on these outside sites.

a. The rules for citing electronic documents as prior art are now available in the paper version of the MPEP, 7th edition, revision 1 dated Feb. 2000 at 707.05(e).

Claim Objections

3. Claim 45 is objected to under 37 CFR 1.75(c), as being of improper dependent form for depending from non-elected claim 41. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Double Patenting

4. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

5. Claims 1-10, 13-18, and 66 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-18 of prior U.S. Patent No. 6,063,628. This is a double patenting rejection.

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 11, 12, 45-50, rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 and 22 of U.S. Patent No. 6,063,628. Although the conflicting claims are not identical, they are not patentably distinct from each other because the methods of increasing the mutation rate of a virus, comprising administering an RNA nucleoside analog to a virally infected cell, wherein the virus is a retrovirus, flavivirus, or pestivirus, and the methods of increasing the mutation rate of a virus in an animal comprising administering to the animal a therapeutically effective dose of a mutagenic ribonucleoside analog composition of the instant application are of substantially the same scope as the methods of increasing the mutation rate of a virus, comprising and RNA nucleoside analog to a virally infected cell of U.S. Patent No. 6,063,628.

Claim Rejections - 35 U.S.C. § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claim 48 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claim 48 recites the limitation "a virus" in line 1. There is uncertain antecedent basis for this limitation in the claim, because it is not clear whether said virus is the same virus recited in line 1 of claim 45, from which claim 48 depends.

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 63 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

a. The specification at p. 31, lines 9-16, discloses the administration of a "drug that reduces the concentration of the natural occurring to be replaced by the ribonucleoside analog."

b. No particular drugs that reduce the concentration of the natural occurring to be replaced by the ribonucleoside analog are taught by the specification as filed. The specification as filed fails to provide any written description at any "drug", or what molecular structures is required to reduce the concentration of the natural occurring to be replaced by the ribonucleoside analog in the invention as claimed. Thus, applicants disclosure combined with what was known in the art is not sufficient to describe the claimed genus of drugs that reduce the concentration of the natural occurring to be replaced by the ribonucleoside analog, by a precise definition, such as by structure, formula, chemical name, or physical properties, and not by a mere wish or plan for obtaining the claimed chemical invention, so as to show applicants were in possession of the claimed invention. *See, Fiers v. Revel*, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993).

12. Claim 64 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

a. The specification at p. 9, lines 15-21, p. 28, lines 21-23, discloses using the free bases of guanine, cytidine, uracil, thymine, and adenine in place of nucleoside analogs to induce mutagenesis of a DNA or RNA virus.

b. The specification does not provide particular guidance or particular direction for the to induce increased mutagenesis of a DNA or RNA virus by the administration of free bases of

guanine, cytidine, uracil, thymine and adenine, other that the mere assertion that it can be done. The remainder of the specification teaches that ribonucleoside analogs are required for making and using the claimed invention. Thus, on its face, the specification appears to contradict the invention of claim 64, and so renders the claimed invention unpredictable. The specification provides no particular nexus between the increased mutagenesis of RNA viruses using ribonucleoside analogs, and the inhibition of the increased mutagenesis of RNA viruses using free bases of guanine, cytidine, uracil, thymine and adenine, other that the mere assertion that they can be used in place of ribonucleoside analogs and the specification provides no other working examples of such.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *Mark L. Shibuya (SRC),* whose telephone number is (703) 308-9355, and/or to the patent analyst, *Katrina Turner*, whose telephone number is (703) 305-3413.
14. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *John LeGuyader* may be reached at (703) 308-0447.
15. Any inquiry of a general nature or relating to the status of this application should be directed to the *Group receptionist* whose telephone number is (703) 308-0196.

Mark L. Shibuya
Patent Examiner
Technology Center 1600
July 30, 2001

SEAN McGARRY
PRIMARY EXAMINER

Attachment for PTO-948 (Rev. 03/01, or earlier)
6/18/01

The below text replaces the pre-printed text under the heading, "Information on How to Effect Drawing Changes," on the back of the PTO-948 (Rev. 03/01, or earlier) form.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

1. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the Notice of Allowability. Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136(a) or (b) for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

2. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes

Timing of Corrections

Applicant is required to submit the drawing corrections within the time period set in the attached Office communication. See 37 CFR 1.85(a).

Failure to take corrective action within the set period will result in **ABANDONMENT** of the application

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